National Institutes of Health
Warren Grant Magnuson Clinical Center
Nursing Department

PROCEDURE: INFUSION OF PRODUCTS FOR CELLULAR THERAPY

Approved by:

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Procedure: Infusion **of Products for Cellular Therapy**

Equipment:
Pre-stamped progress notes (2)
Primary IV tubing (2)
Universal Secondary Tubing
Three-way Stopcock (optional)
Sodium Chloride 0.9% 250cc (2 bags)
Infusion pump (optional)
Hard candies/ Room deodorizer/ Orange slices (order from Dietary)
Box of gloves

Emergency Spill Equipment to have at bedside:
Sterile gloves (2 pairs)
Sterilized straight 5-1/2" hemostats (4)
Alcohol swabs

PRE-INFUSION

Steps:	**Key Points/ Rationale**
1. Call the Cell Processing Lab (CPL) at 5-4801 by 3pm the day before the cells are ordered to be infused in order to confirm the schedule, number of bags/syringes, and type of product to be administered.	1. Most cell infusions will be scheduled in advance. Donor lymphocyte infusions may occasionally be ordered and/or cancelled on short notice due to individual patient situation. If a cell infusion is scheduled for a Monday, call Friday prior.
2. Verify physician's order: • to administer cellular products • for date of administration • for premedication orders. Any changes from the original infusion schedule must be approved by CPL.	2. Premedication will only be given to patients receiving cryoperserved cells. Premedication will typically consist of IV Benadryl, as the DMSO preservative causes a histamine release.
3. Verify informed consent has been obtained for blood product administrations.	
4. Ensure emergency equipment is available in patient's room: a. Normal saline flush solution b. Oxygen c. Suction machine d. Vital sign monitor e. Emergency spill equipment	
5. Verify that emergency medications are readily available in the area where patients will receive treatment.	
6. Prepare room with deodorizers for patients receiving cryopreserved cells.	6. DMSO, the preservative used when freezing the cellular product, has an odor that may be unpleasant.
7. Measure and record vital signs (T/P/R/BP with	

oxygen saturation, as clinically indicated), pulmonary assessment, and circulatory assessment.	
8. Provide patient education including infusion process, potential complications and associated symptoms to report.	
9. Review renal function tests and CBC with treatment team.	9. Based upon certain laboratory parameters, the prescriber may choose to implement certain orders, e.g. aggressive hydration, because DMSO may affect renal function, as can the hemolysis of RBC's in the product.
10. Verify patency of IV access.	10. It is recommended to use a CVC for infusion of cellular products, but peripheral access is acceptable.
11. Start an IV infusion of 250cc 0.9% NS at KVO to function as emergency/hydration line. Use primary infusion pump tubing and connect it hub to hub to the VAD lumen directly or via three-way stopcock.	11. This emergency line can also be used for administration of IV premedications.
12. Initiate Intake/Output record if indicated.	
13. Administer premedications as ordered.	13. Allow 30-60 minutes for oral medications, 10-30 minutes for IV medications to become effective.
14. Notify CPL when the patient is ready to receive the first unit of cells. Speak to the technologist performing product preparation and delivery. Provide patient's name, ID number and location	
15. When the CPL tech delivers the thawed product to floor, the RN and tech will confirm product number, patient's name, and bag #. RN will initial "Cryopreserved product selection and thaw record," documenting receipt of the product.	

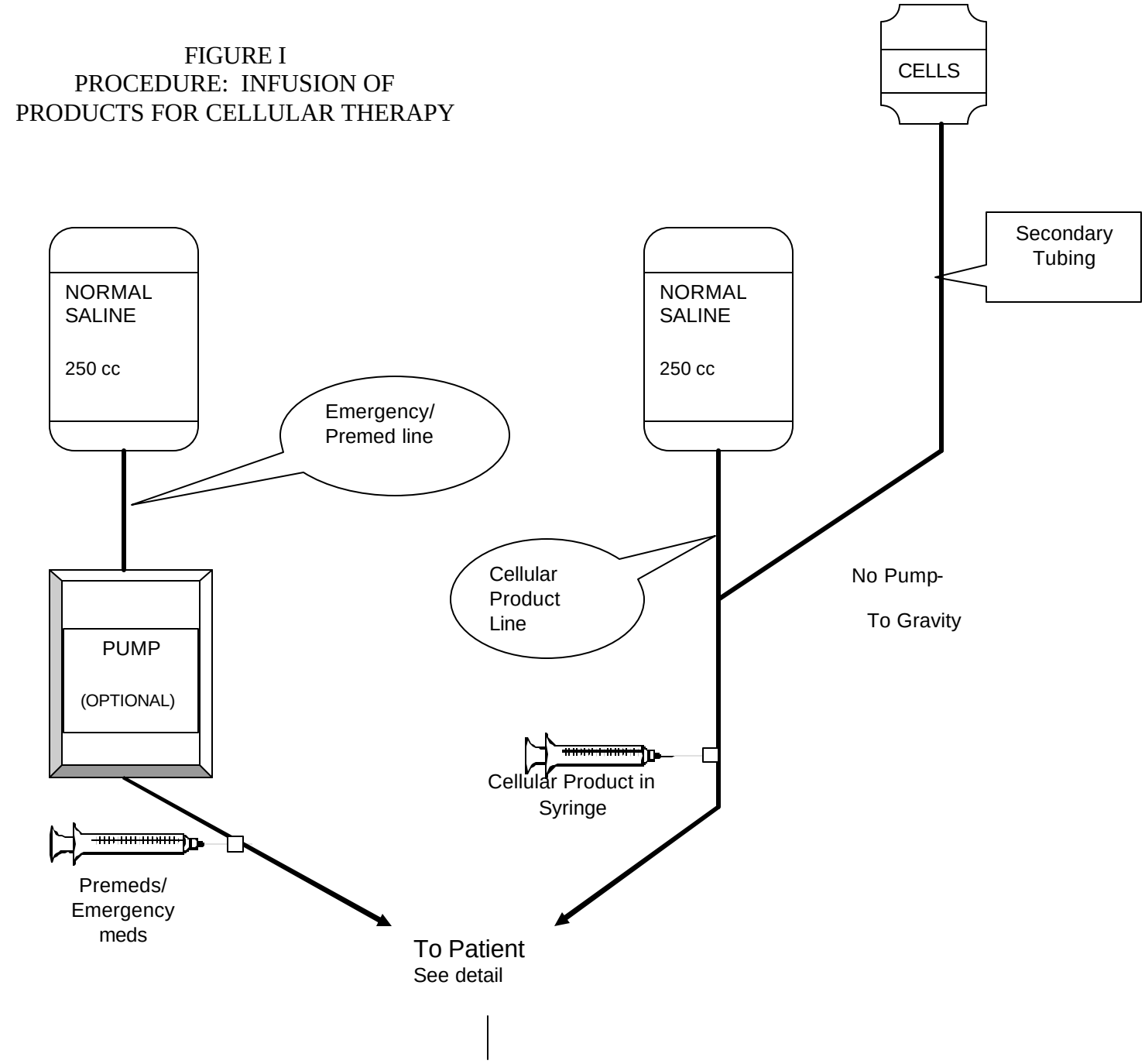
INFUSION:

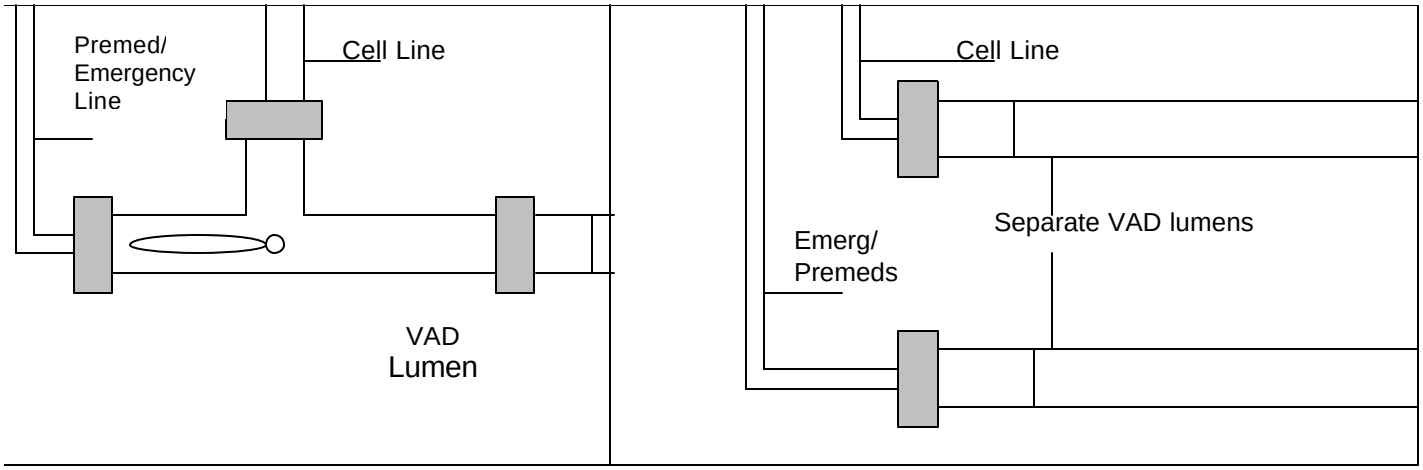
Steps:	**Key Points/ Rationale**
1. Connect a second primary line of NS to the patient. This can be done either via a three-way stopcock or directly to a lumen separate from the emergency line.	1. This will serve as the dedicated cellular product infusion line. Do not infuse any other substances into cell infusions; prime and back flush only with NS. Infuse any premedications or other substances into emergency line of NS. DO NOT use filter on cell infusion line unless one is provided by CPL.

2. At the bedside, 2 qualified individuals will perform identification procedure with cellular product immediately prior to spiking bag or connecting syringe as outlined in the CCND Blood Administration Procedure.	
3. The RN will notify the patient's prescriber when cells are being infused. The prescriber will be immediately available on the unit.	
4. Observe each product for unusual color, appearance or temperature. Call CPL with any questions or concerns regarding the component.	
5. <u>Syringe infusion:</u> Connect the syringe to the most distal port of the primary IV tubing designated for cellular products and administer cells IVP as tolerated by patient. When completed, backflush the syringe with NS and infuse the dilute solution. Repeat until all syringes containing product have been infused. <u>Bag infusion:</u> Spike the cellular product bag with secondary tubing (do not prime the tubing with cellular product). Connect the secondary tubing to the primary normal saline line designated for cellular therapy, and use backflush technique to prime the secondary tubing with normal saline. Infuse the cellular product to gravity as tolerated by patient. When bag is empty, backflush secondary tubing with enough NS to rinse bag. Infuse the diluent. **See Figure 1 for Diagram of Set-Up**	5. Backflushing either the syringe or bag of cells and then reinfusing the dilute solution will ensure that all cells are administered to the patient. In order to allow for backflushing secondary tubing must be used. Expect facial flushing at the start of each bag. Slow infusion; flushing will resolve within several minutes and does not usually require additional medication.
6. Measure and record TPR, BP and (oxygen saturation if clinically indicated), before and after each bag/syringe has been infused.	6. If bag infusion takes longer than 15 minutes, measure and record vital signs at 15 minute intervals.
7. After each bag/syringe has infused, remove the adhesive backed "Cell therapy product" tag from the bag/syringe and place on progress note in patient's medical record.	7. Placing the adhesive product tag in the patient's record is in addition to, and does not replace, documentation in MIS. CPL will have completed left-hand side of label prior to delivery of product. At completion of infusion, RN will complete right-hand side of label with start time, end time, and initials of infusionist.
8. If more than one bag/syringe is to be infused, contact CPL at 5-4801 at the completion of each unit. CPL will prepare and deliver the	8. Once thawed, survival time of cells is very short. Cell infusion must be initiated immediately after thawing. Do not request next unit of cells until

next unit of cells.	previous unit is complete.

FIGURE I
PROCEDURE: INFUSION OF
PRODUCTS FOR CELLULAR THERAPY





POST INFUSION:

Steps:	**Key points/ Rationale:**
1. Check TPR, BP and (oxygen saturation if clinically indicated) after all units of cells have been infused.	.
2. Outpatients may be released thirty minutes to one hour after completion of infusion if vital signs are stable.	.
3. Reinforce discharge instructions; in particular, when to notify health care team.	.

DOCUMENTATION

1. Using "Cell therapy product" tag, indicate sequence of bag number, ex., #1, #2, etc. Document product number, volume, vital signs, and patient's response after each product. Utilize the blood component pathway in MIS.
2. Record premedications given, intra-infusion medications, product volumes and summary note of patient's response in the medical record under nursing assessment pathway.

TRANSFUSION REACTIONS

If at anytime during infusion the patient exhibits s/s of transfusion reaction the following actions should be taken:

1. Discontinue the infusion of cells. DO NOT disconnect or discard the cellular product.	.
2. Keep the emergency line open at KVO.	2. Emergency medications can be administered through this line if required.
3. Notify the prescriber immediately	.
4. Administer emergency medications as ordered by prescriber.	.
5. Follow CCND Blood Product Administration Procedure for transfusion reaction **Exception**: DO NOT return the bag or syringe of cellular product to DTM. Leave the product connected to the cellular product line.	5.
6. Contact CPL staff who will determine how to preserve the cells until the infusion is resumed or re-initiated at a later time.	

TECHNICAL COMPLICATIONS

In the event of a bag leakage or puncture:

1. When a bag has been punctured in the process of inserting a spike, **do not** attempt to remove the spike from the bag.
2. Close off tubing to the bag using integral clamp or hemostat.
3. Use 2 hemostats to isolate the area of the puncture as shown on attached photo. Keep the bag upright with the punctured area at the top. **Do not squeeze the bag**!
4. Telephone the CPL technologist responsible for the product at **ext. 5-4801**. Explain that the bag has been damaged and that someone is needed **immediately** to retrieve the cells.
5. Put on a new pair of sterile gloves and wipe the outside of the bag with alcohol.
6. When the technologist arrives, he/she will transport the product to the CPL for evaluation and, if possible, for transfer to another container.
7. The technologist will inform the Chief of CPS who will confer with the recipient's physician to determine whether the product can safely be infused.
8. The incident should be documented on the patient's chart as well as in the CPL records. An occurrence should be filed in the Occurrence Reporting System.

REFERENCES

1. Areman, E. Salvage of Cell Therapy Product from Punctured Bag, Bethesda, MD. 2000
2. American Association of Blood Banks, Second Standards for Hematopoietic Progenitor Cell Services, 2000
3. American Association of Blood Banks, American Red Cross, American Blood Centers. Circular of Information for the use of Hematopoietic Progenitor Cell Products. Bethesda, MD: American Association of Blood Banks, 2000.
4. Foundation for the Accreditation of Hematopoietic Cell Therapy, Standards for Hematopoietic Progenitor Cell Collection, Processing, and Transplantation 1st ed., 1996.
5. Georgetown University Hospital Bone Marrow, Peripheral Blood Stem Cells, Peripheral Blood Leukocytes and Granulocytes for Infusion Procedure
6. National Institutes of Health, Clinical Center, Nursing Department. Administration of Blood and Blood Products Procedure. Bethesda, MD, 2000
7. Oncology Nursing Society Peripheral Blood Stem Cell Transplantation: Recommendations for Nursing Education and Practice

ATTACHMENT A: **Infusion of Products for Cellular Therapy**